

**Notice of Allowability**

Application No.

09/995,419

Examiner

Joseph T. Voitach

Applicant(s)

MCWHIR ET AL.

Art Unit

1632

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/18/2004.
2. ☒ The allowed claim(s) is/are 1-15 and 23-47.
3. ☒ The drawings filed on 26 November 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☒ hereto or 2) ☒ to Paper No./Mail Date 7.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

This application filed November 26, 2001 claims benefit to provisional applications: 60/253,357, filed November 27, 2000; 60/253,443, filed November 27, 2000; and 60/253,395, filed November 27, 2000.

Applicants' amendment filed, 2004, has been received and entered. The specification has been amended. Claims 16-22 have been canceled. Claim 41-43, 46 and 47 have been amended. Claims 1-15, 23-47 are pending.

### ***Election/Restriction***

As indicated previously, Applicant's election with traverse of Group III in Paper No. 11 was acknowledged. The traversal was found persuasive and groups I and III were rejoined, and the election of species was withdrawn.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

Applicants arguments and supporting references have been fully considered, and found sufficient to obviate the remaining rejection of record. As indicated previously, the claims are free of the art of record because while the art supports using identification and purification techniques for the isolation of stem cells, it does not disclose using heterologous markers expressed preferentially in these cells in conjunction with differentiation protocols to selectively

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exclude the presence of stem cells in the final composition. In the prior art, the methods of obtaining and maintaining pluripotent stem cells in culture focused primarily on optimizing conditions that maintained the undifferentiated state of the stem cell. In complimentary methodology using the isolated stem cells, the prior art focused obtaining specific culturing conditions for directed differentiation of the stem cells. At the time of filing it was recognized that the conditions available to differentiate a stem cell resulted in a population of cells in which undifferentiated stem cells could exist. The instant specification teaches materials and methods for selectively depleting the remaining undifferentiated stem cells in a culture to obtain a population of differentiated stem cells free of undifferentiated stem cells. More specifically, the specification provides the necessary guidance to genetically modify a stem cell with a heterologous nucleic acid sequence wherein the selective expression of the sequence in undifferentiated stem cells after differentiating the population results in a surface antigen that can be used in a variety of selection methods to deplete the remaining undifferentiated stem cells. The specification provides a variety of stem cell specific promoters which can be operatively linked to sequences that will encode and/or result in a unique antigen present on the cell surface of the stem cell.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

JOSEPH WOITACH  
PATENT EXAMINER

*Joe Woitach*  
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